

Opening Statement of Rep. Edward J. Markey (D-MA)
Oversight and Investigations Subcommittee Hearing
Flu Vaccine: Protecting High-Risk Individuals and Strengthening the Market
Thursday, November 18, 2004

Mr. Chairman, thank you for holding this important hearing on the flu vaccine shortage. Just yesterday, hundreds of seniors in my district stood in long lines at the Elks Lodge in Natick to put their name on a list for their upcoming flu clinic. In Massachusetts, we are hoping that registration programs like this one will help us target our scarce resources and ensure that the most vulnerable individuals get their flu shots first. But many of my constituents won't be able to get the flu vaccine this year. They are worried and they want to know how the federal government and the pharmaceutical industry have allowed such a state of affairs.

Today we will hear from several witnesses about the problems at the Chiron manufacturing plant, and the events which led to the loss of half of the U.S. supply of flu vaccine. Today's news reports suggest that the FDA may have failed to properly exercise its responsibilities to ensure that Chiron's flu vaccine manufacturing facilities met appropriate safety and health standards. These reports are profoundly disturbing and I hope to learn why, if the FDA knew that Chiron had problems in June 2003, the agency they failed to promptly follow up with the company and ensure that the problems the FDA staff had identified at the plant were immediately corrected.

I am also concerned that the flu vaccine crisis is indicative of a larger problem at the FDA and in the pharmaceutical industry. Approximately 36,000 people die and 200,000 people are hospitalized every year due to complications from influenza. It is a disease that, while variable in its form, its yearly presence is as predictable as the changing seasons. Yet despite the ancient and cyclical nature of this threat, and despite repeated warnings and recommendations from the National Vaccine Advisory Committee, the Institute of Medicine, and the Government Accountability Office, the Bush Administration does not have a system in place to protect the American public from the flu and the possibility of a flu epidemic. How is it that they allowed a problem at a single plant to eliminate half of our yearly supply of vaccine without a contingency plan to ensure that the American public has access to an adequate supply of flu vaccine? We need answers.

Ten years ago there were five suppliers of flu vaccine; today the US relies on two manufacturers to produce 95% of all our flu vaccine. This means that if a problem arises at one of the plants, it can significantly disrupt the supply of flu vaccine. Just as you shouldn't put all your eggs in one basket, the US should not grow all of its flu vaccine eggs at one company. We must find other companies who are willing to add to the future supply of the flu vaccine. Therefore, it is critical that we learn why companies have left the vaccine business and what steps we can take to change that trend.

The pharmaceutical industry tells us that the high cost of many prescription drugs is justified by the expenses associated with developing new drugs. But if the private sector has concluded that producing new flu vaccines every year is not something they wish to do because it is not sufficiently profitable, we must ask just what are they using their massive prescription

drug profits for? If we cannot rely on private sector drug manufacturers to produce the flu vaccine we need in the U.S. each year, do we need to rethink the federal government's entire relationship with this industry in some very fundamental ways?

Today we are going to focus primarily on how we got here and what we can do to get the public through this upcoming flu season. However, it is my hope that the conversation will not end here. I look forward to further hearings on this subject and working with my colleagues to develop a comprehensive solution to the larger problem of guaranteeing a stable and adequate supply of vaccine.

Thank you.